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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,247	07/25/2003	Sean D. Monahan	Mirus.007.01.2	4188

7590 09/08/2004
Mark K. Johnson
Mirus Corporation
505 S. Rosa Rd.
Madison, WI 53719

EXAMINER

GUZO, DAVID

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/627,247

Applicant(s)

MONAHAN ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/17/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Detailed Action

Priority

Applicants claim priority to 09/354,957 (filed 7/16/99, issued 8/6/02) on the first page of the specification. This priority claim is not granted because there is no chain of continuity between the instant application filed 7/25/03, and the date of issue of the 09/354,957 parent (8/6/02).

It is noted that applicants, in the Transmittal papers for the instant application, indicate that the instant application is a Divisional of parent application 10/081,461. However, a proper claim for priority requires that said priority claim be present on the first page of the specification or on a timely filed application data sheet (ADS).

It is noted that this application appears to claim subject matter disclosed in prior Application No. 10/081,461, filed 2/21/02. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the

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national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Disclosure

The disclosure is objected to because of the following informalities: A Drawing is present on Page 39 of the specification. Applicants are required to delete the Figure from the specification and submit it as a Drawing.

Appropriate correction is required.

35 USC 102 Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-19 and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Bolcsak et al.

Applicants claim a process for forming a complex that is deliverable to a cell, comprising inserting a cargo into a reverse micelle consisting of one or more amphipathic molecules wherein at least one of the amphipathic molecules contains a labile bond, a reactive functional group, capable of participating in a polymerization reaction or a disulfide bond and a reactive functional group capable of participating in a polymerization reaction. The amphipathic molecule can also contain an amide constructed from a compound having a substructure of succinic anhydride. Applicants also claim a negatively charged, zwitterionic or neutral compound that is deliverable to a mammalian cell comprising a negatively charged neutral or zwitterionic micelle containing a biologically active compound.

Bolcsak et al. (U.S. 5,100,662, issued 3/31/92, see whole document, particularly Fig.1, column 5, lines 60-68; column 6, lines 10-25; column 10, lines 24-69; column 11;

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column 13, lines 33-68; column 14, lines 9-68; Example 5) recites a method for forming a complex that is deliverable to a mammalian cell comprising inserting a cargo (which can be a biologically active compound such as a protein, nucleic acid, etc.) into a reverse micelle consisting of one or more amphipathic molecules wherein at least one of the amphipathic molecules contains a labile bond (i.e. a bond capable of being destroyed), a reactive functional group (which can be charged groups such as a tertiary or quaternary amines, sulfonates, etc.) which is capable of participating in a polymerization reaction (the reactive functional groups on the derivatized sterol molecules or the phospholipids recited in Column 14 can be capable of participating in a polymerization reaction) or contains a disulfide bond and a reactive functional group capable of participating in a polymerization reaction. The amphipathic molecule can also contain an amide constructed from a compound having a substructure of succinic anhydride. Bolcsak et al. also recites neutral or charged reverse micelles that are deliverable to mammalian cells and wherein said micelles contain a biologically active compound. Bolcsak et al. therefore teaches the claimed invention.

Claims 14-15 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Imre et al.

Applicants claim a process for forming a complex deliverable to a cell comprising inserting a cargo into a reverse micelle consisting of one or more amphipathic molecules wherein at least one of the amphipathic molecules contains a labile bond and a functional group. Applicants also claim a negatively charged compound which is deliverable to a mammalian cell comprising a negatively charged micelle containing a biologically active molecule.

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Imre et al. (Biochem. Biophys. Res. Comm., 1982, Vol. 107, No. 2, pp. 538-545, see whole article, particularly the Summary and pages 538-539) recites a process for forming a complex deliverable to a cell comprising inserting into a reverse micelle consisting of an amphipathic molecule (di(2-ethyl-hexyl) sodium sulfosuccinate (AOT)) containing a labile bond (i.e. S-O bond) and a functional group (SO₃-X). Imre et al. also recites a negatively charged (anionic) micelle (comprising AOT) containing a biologically active molecule (nucleic acid). Imre et al. therefore teaches the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Grinstaff et al.

Both applicants and Grinstaff et al. (US 2002/0035082, Published 3/21/02, priority to 6/9/00, issued as U.S. Patent 6,696,081, see whole document, particularly the abstract, paragraphs 15-19, 72-73, 81, 83, Claim 1) recite a process for forming a reverse micelle consisting of one or more amphipathic molecules containing a labile bond (i.e. a methylene, an ether, etc.), a reactive functional group (i.e. a thiophosphate, an ether, etc., see Claim 1) which is capable of participating in a polymerization reaction (the lipid compound of Claim 1 has several sites which can participate in a

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polymerization reaction and wherein the amphipathic molecules can contain a silicon-heteroatom bond (paragraph 19). Grinstaff et al. also teaches negatively charged or zwitterionic micelles containing a biologically active compound (Example 1 teaches a zwitterionic phospholipid used to form micelles and the amphipathic molecules disclosed by Grinstaff et al. can have a negative charge as a result of anionic groups such as phosphate (PO_4^-) groups. Grinstaff et al therefore teaches the claimed invention.

It is noted that priority for the subject matter in the instant claims is granted back to the filing date of the instant application.

Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 26 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-9 of U.S. Patent No. 6,429,200 (hereafter the '200 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of claim 26 is generic to all that is claimed in the '200 patent. In other words, the subject matter in claims 1-9 would anticipate the claimed invention. Specifically, the negatively-charged, zwitterionic or neutral reverse micelles containing nucleic acids claimed in the '200 patent are encompassed within the instantly claimed negatively-charged, zwitterionic or neutral micelles which comprise any biologically active material. It is noted that the intended use language (for delivery to a cell) imparts no patentable weight to the composition claims.

Claims 14-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,673,612 (hereafter the '612 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the instant claims is generic to all that is claimed in the '612 patent. In other words the subject matter of the '612 patent would anticipate the instant claims. Specifically, both sets of claims recite a process for forming a reverse micelle that is deliverable to a cell, comprising inserting a molecule into the reverse micelle wherein said micelle is comprised of one or more amphipathic molecules which contains a labile bond, a

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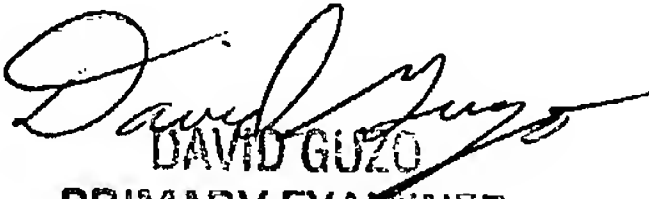
reactive functional group or a disulfide bond or a group capable of participating in a polymerization reaction or a silicon-heteroatom bond, etc. It is noted that the instant claims recite inserting a "cargo" into the micelle while the claims of the '612 patent recite inserting a "biologically active compound" into the micelle. The specification defines "cargo" as comprising pharmaceuticals, proteins, peptides, hormones, etc. and it must therefore be considered that the term "cargo" encompasses biologically active compounds.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


DAVID GUZO
PRIMARY EXAMINER

David Guzo
September 2, 2004